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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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06/22/2001

Anthony J. Kinney

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04/21/2005

E I DU PONT DE NEMOURS AND COMPANY  
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WILMINGTON, DE 19805

EXAMINER

ASHEN, JON BENJAMIN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/887,194	KINNEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2004 has been entered.

### ***Status of the Application***

2. Claims 46-52 are pending in this application. Claims 1-45 were cancelled by Applicant in the communication filed 10/29/2004. Claims 46-52 are currently under examination in this Application.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 46-48 and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 46-48 and 50-51 are indefinite due to the recitation "do not share sequence identity with any endogenous RNA in soybean". It is unclear what degree of difference is required to meet this claim limitation and how an

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RNA cannot share sequence identity with any endogenous RNA in soybean at even one residue, for example.

5. Claims 46-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 46-52 are drawn to nucleic acid constructs and methods that reduce the expression of target mRNAs or any endogenous mRNAs expressed in soybean that have at least 80% sequence identity with a sequence homologous to all or part of the target mRNA, wherein the determination of sequence identity is recited as being "based on the Clustal method of alignment." However, the metes and bounds of what is being claimed cannot be determined because there is no single Clustal method of alignment and the claim language does not specify the requisite parameters that would define the claimed method of Clustal alignment. The method of aligning multiple sequences, using the Clustal algorithm, can have highly variable results depending on the parameters used, such as the clustal size and the gap length, for example.

6. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 recites, "A method for reducing the expression of a target mRNA or any endogenous mRNA that has at least 80% sequence identity with the sequence homologous to all or part of the RNA homologous to the target mRNA,

expressed in soybean based on the Clustal method of alignment, the method comprising:..". In the instant case, the metes and bounds of what is being claimed cannot be determined because it is unclear what is being claimed. As written, this claim reads on a method for reducing the expression of an mRNA wherein the method is expressed in soybean and it is not clear how a method can be expressed in soybean. Moreover, this claim is drawn to an mRNA that has at least 80% sequence identity with a sequence that is homologous to the RNA that is homologous to itself. The language of this claim is very unclear, rendering this claim indefinite.

7. Claim 48 recites the limitation "said sequence" in line 8. There is insufficient antecedent basis for this limitation in the claim because multiple sequences are referred to in the preceding lines.

8. Claim 49 recites the limitation "the target mRNA expressed in soybean" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 52 recites the limitation "the RNA" in line 3. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 52 recites the limitation "the RNA" in 8. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 52 recites the limitation "the sequence" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim because sequence does not appear the preceding lines.

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12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 46-47 and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 46-47 and 49-52 recite specific portions of SEQ ID NO: 13 which are new limitations to the claims introduced by amendment in the communication filed 10/29/04. Applicant has indicated, in the remarks filed 10/29/04, where support for the newly added limitations of particular regions of SEQ ID NO: 13 can be found in the specification (pg. 18, lines 12-34 and pg. 2, lines 34-36). However, no support for the newly added limitations of particular regions of SEQ ID NO: 13 could be located in the specification and claims as originally filed, including the particular parts of the specification pointed to by Applicant. If Applicant believes that particular support for the newly added limitations of particular regions of SEQ ID NO: 13 is to be found in the specification or claims as originally filed, Applicant should point, with particularity, to where such support may be found.

14. Claims 46-52 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 46-52 are broadly drawn to compositions and methods comprising a vast genera of recombinant constructs and the RNA's that are expressed from such that reduce the expression of target mRNAs or any endogenous mRNAs expressed in soybean that have at least 80% sequence identity with a sequence homologous to all or part of the target mRNA, wherein the determination of sequence identity is recited as being "based on the Clustal method of alignment." Claims 49 and 52 are drawn to methods for reducing expression of a target mRNA or any endogenous RNA using the constructs or RNA of claims 46-48 and 50-51. However, the specification as filed does not provide an adequate written description of the broad genera of constructs or RNAs expressed from such that is commensurate with the breadth of what is now claimed, that will function to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean wherein the determination of sequence identity is recited as being "based on the Clustal method of alignment." It is noted here that the claim language in (a), "at least one target mRNA expressed in soybean, is not limited to genes that are encoded by the genome of soybean or "endogenous" to soybean but, as written, reads on any target mRNA expressed in soybean.

The specification as filed provides only a general disclosure of what is encompassed any target mRNA that can be expressed in soybean, the expression of which can be reduced by an RNA or the expression of an RNA having 80% homology to all or part of said target mRNA based on the Clustal method of alignment or any endogenous gene the expression of which can be reduced by an RNA or the expression of an RNA having 80% homology to all or part of said endogenous mRNA based on the Clustal method of alignment. In regards to the Clustal method of alignment, the specification provides only a general disclosure of the method by providing the original literature citation. The specification discloses a single example of the method wherein the variable parameters of the algorithm are set to default. The specification does not provide a limiting definition of what is encompassed by "the Clustal method of alignment" and the state of the art as shown by the citation provided by Applicant (Higgins and Sharp 1989, as cited in the specification on page 13), recognizes that the results obtained from the multiple alignment of nucleotide sequences using the Clustal method can be variable depending on the settings of the initial parameters such as clustal size, gap penalty, gap length penalty, for example.

The specification provides general guidance and several examples of target mRNAs and endogenous mRNAs, the expression of which are reduced in soybean, but does not indicate or disclose any distinguishing identifying characteristics of these mRNAs that would indicate that applicant was in possession of these broadly claimed genera of constructs and RNAs commensurate with what is now claimed, that will function to reduce the expression of any target mRNA or any endogenous RNA



expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean wherein the determination of sequence identity is recited as being "based on the Clustal method of alignment." However, general guidance and examples provided by the specification are insufficient to indicate possession of the broadly claimed genera of constructs and RNAs as claimed. The specification does not provide the specific guidance that would be required to reasonably lead one of skill in the art to the claimed invention or that would allow the skilled artisan to recognize that Applicant was in possession of the broad genera that functioned commensurate with what is now claimed: nucleic acid constructs and RNAs that comprise a sequence homologous to and that reduces the expression of any nucleotide sequence that is at least 80% homologous to all or part of any target mRNA (which can be any RNA from any source) which can be expressed in soybean or any endogenous mRNA expressed in soybean. Moreover, and, in light of the 112 2<sup>nd</sup> paragraph rejection set forth previously in this Action, the metes and bounds of what is being claimed by a nucleotide sequence that has at least 80% sequence identity to another sequence wherein the degree of sequence identity is determined by a method that is highly variable depending on the settings of the initial parameters, cannot be determined.

What is the structure of a construct or an RNA expressed from such, for example, that will function commensurate with what is now claimed, that will function to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or

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part of the RNA having homology to at least one target mRNA expressed in soybean wherein the determination of sequence identity is recited as being "based on the Clustal method of alignment."

MPEP § 2163[R-2] I. states:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); < Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

In the instant case, Applicant has not provided adequate written description of their invention because the specification does not convey, with reasonable clarity to those of skill in the art, as of the filing date sought, that applicant was in possession of what is now claimed. Applicant has not shown how the invention was "ready for patenting" such as by the disclosure of the structure of a construct or RNA expressed

from such that would function commensurate with the breadth of what is now claimed (that shows that the claimed invention was complete), or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the broad genera as claimed.

15. Claims 46-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for constructs, RNAs expressed from such and methods of using constructs and RNAs expressed from such for reducing the expression of *fad2*, *delta9*, *gas1* and *gas2* in soybean, does not reasonably provide enablement for constructs, RNAs expressed from such and methods of using constructs and RNAs expressed from such to reduce the expression of any target mRNA or any endogenous RNA expressed in soybean that has at least 80% sequence identity with a sequence homologous to all or part of the RNA having homology to at least one target mRNA expressed in soybean wherein the determination of sequence identity is recited as being "based on the Clustal method of alignment." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), are considered when making a determination that a disclosure is not enabling: the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples

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and the quantity of experimentation needed to make the invention based on the content of the disclosure.

In the instant case, claims 46-52 are broadly drawn to subject matter that has not been adequately described in the specification such that one of skill in the art can neither determine the metes and bounds of what is now claimed nor clearly recognize that Applicant was in possession of the invention commensurate with what is now claimed (as outlined in previous rejections herein). Given the lack of definiteness in the claims and the lack of written description in the specification, although the level of ordinary skill in the art is acknowledged as quite high, one of skill would still require specific guidance to practice the claimed methods, with the resultant specified biological effect of gene inhibition, commensurate in scope with what is claimed. However, the specification does not provide the requisite guidance such that any person skilled in the art would be able to make the instantly claimed constructs or RNAs expressed from such or to practice the claimed methods commensurate with their full scope, without performing undue *de novo* trial and error experimentation. This experimentation would be required, at least, to identify and characterize the vast number of target mRNAs and endogenous mRNAs, the expression of which could be reduced in soybean by the nucleic acid constructs, RNAs and methods of the invention that comprise and employ a sequence homologous to and that reduces the expression of any nucleotide sequence that is at least 80% homologous to all or part of any target mRNA (which can be any RNA from any source) which can be expressed in soybean or any endogenous mRNA expressed in soybean.

Thus, while the specification is enabling for the examples set forth in the disclosure, the specification is not enabling for the full scope of what is now claimed. Thus, one of skill in the art could not practice the invention commensurate in scope with the claims without undue, *de novo* trial and error experimentation. Additionally, the type of experimentation required to practice the invention more broadly that is exemplified is a factor in the enablement analysis, but is not dispositive. In this case, even if the nature of each experiment required to expand the scope of the enabled invention was considered standard (which it is not), it would be out weighted by the sheer quantity of experimentation required to practice the full scope of the claimed invention.

### ***Conclusion***

16. No claims are allowable

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba

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